



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Tae H. Ji et al.

Application No.: 10/821,939

Filing Date: April 12, 2004

Title: AGENTS AND METHODS FOR MODULATING INTERACTIONS BETWEEN GONADOTROPIN  
HORMONES AND THEIR RECEPTORS

Group Art Unit: 1649

Examiner: CHRISTINA M BORGEEST

Confirmation No.: 2139

AMENDMENT/REPLY TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed is a reply for the above-identified patent application.

☐ A Petition for Extension of Time is also enclosed.

☐ Terminal Disclaimer(s) and the ☐ \$65.00 (2814) ☐ \$130.00 (1814) fee per  
Disclaimer due under 37 C.F.R. § 1.20(d) are also enclosed.

☒ Also enclosed is/are a return receipt postcard

☒ Small entity status is hereby claimed.

☐ Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the  
☐ \$395.00 (2801) ☐ \$790.00 (1801) fee due under 37 C.F.R. § 1.17(e).

☐ Applicant(s) requests that any previously unentered after final amendments not be entered.  
Continued examination is requested based on the enclosed documents identified above.

☐ Applicant(s) previously submitted \_\_\_\_\_  
\_\_\_\_\_ on \_\_\_\_\_  
for which continued examination is requested.

☐ Applicant(s) requests suspension of action by the Office until at least \_\_\_\_\_,  
which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R.  
§ 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.

☐ A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also  
enclosed.

**Buchanan Ingersoll PC**

ATTORNEYS

Including attorneys from Burns Doane Swecker & Mathis

- ☒ No additional claim fee is required.
- ☐ An additional claim fee is required, and is calculated as shown below.

AMENDED CLAIMS					
	No. of Claims	Highest No. of Claims Previously Paid For	Extra Claims	Rate	Additional Fee
Total Claims	53	MINUS 53 =	0	x \$50.00 (1202) =	\$ 0.00
Independent Claims	22	MINUS 22 =	0	x \$200.00 (1201) =	\$ 0.00
If Amendment adds multiple dependent claims, add \$360.00 (1203)					
Total Claim Amendment Fee					\$ 0.00
<input checked="" type="checkbox"/> Small Entity Status claimed - subtract 50% of Total Claim Amendment Fee					\$ 0.00
<b>TOTAL ADDITIONAL CLAIM FEE DUE FOR THIS AMENDMENT</b>					<b>\$ 0.00</b>

- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the fee due.
- ☐ Charge \_\_\_\_\_ to Deposit Account No. 02-4800.
- ☐ Charge \_\_\_\_\_ to credit card. Form PTO-2038 is attached.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

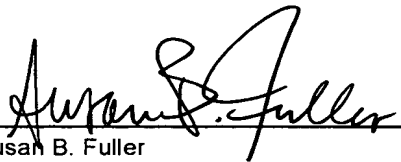
Respectfully submitted,

BUCHANAN INGERSOLL PC

12230 El Camino Real  
Suite 300  
San Diego, CA 92130-2090  
(858) 509-7300

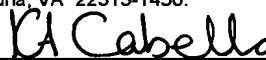
Date: September 22, 2005

By

  
Susan B. Fuller  
Registration No. 51,979

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date of Deposit: September 22, 2005



Kim A. Cabello  
Typed Name:



## Patent

In re Patent Application of

Group Art Unit: 1649

Examiner: CHRISTINA M. BORGEEST

Confirmation No.: 2139

## Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, on September 22, 2005, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

By:

Kim A. Cabello

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Response is being submitted in response to the Restriction Requirement of August 23, 2005. Accordingly, this response is timely filed.

In the Restriction Requirement, the Examiner sets forth a restriction requirement among seventeen (17) groups of the claims. Applicants elect Group III, Claims 16-17, in part, and 18, drawn to a method of contraception in a female subject comprising administering an agent that modulates CG or CG interaction with exoloop 1, exoloop 2 or exoloop 3 of the LHR, classification dependent on structure of recited "agent", ***with traverse***.

The Applicants traverse the Restriction Requirement for at least the following reasons. Under M.P.E.P. § 803, a restriction is proper if the subject matter can be restricted into one of two or more claimed inventions, and these inventions are either independent

(M.P.E.P § 806.04) or distinct (M.P.E.P § 806.05). However, the second element for a restriction requirement to be proper is that if the search and examination of an entire application can be made without serious burden, the Examiner must examine the entire application on the merits, even though it includes claims to independent and distinct inventions.

Applicants respectfully submit that the inventions of Groups I to XVII are closely related and that a proper search of any of the claims should, by necessity, require a proper search of the others. For example, Groups VIII and XVI are so related that the Office identifies them in the same class and subclass (i.e., class 424, subclass 130.1). Groups I to XVII share the special technical feature of relating to modulating gonadotropin hormones and related gonadotropin hormone diseases. Thus, all of the claims can be searched simultaneously, and that a duplicative search, with possibly inconsistent results, may occur if the restriction requirement is maintained, particularly where the groups comprise the same class, subclass. Applicants submit that any nominal burden placed upon the Examiner to search accordingly to determine the art relevant to Applicants' overall invention is significantly outweighed by the public's interest in not having to obtain and study many separate patents in order to have available all of the issued patent claims covering Applicants' invention. The alternative is to proceed with the filing of multiple applications, each consisting of generally the same disclosure, and each being subjected to essentially the same search, perhaps by different Examiners on different occasions. This process would place an unnecessary burden on both the Patent and Trademark Office and on the Applicants.

## 2. SPECIES ELECTION

The Examiner further sets forth two groups of species: Part I: Stimulation of Hormones, Tissues and Cells (I a-f), and Part II: Diseases (II a-r). Applicants are required to further elect a single disclosed species. Applicants submit that the elected invention (i.e., Group III, claims 16-18) do not recite any of the elected species set out in the Restriction Requirement. However, to be fully responsive with the Restriction Requirement, Applicants provisionally elect, *with traverse*, Part I-c) stimulation of development of the female gonads, follicles, and maturation of oocytes, for the purpose of searching only. It is believed that claim 16 is readable upon the elected species, stimulation of development of the female gonads, follicles, and maturation of oocytes.

The Examiner is reminded of *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) in which the court articulated the general proposition that:

[A]n applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *Id.* at 331 (Emphasis in original).

In view of the above and similar case law, the Patent Office has set forth a general policy regarding restriction of Markush-type claims in MPEP § 803.02. According to the general policy as articulated in the MPEP, “since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334, it is **improper** for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ

300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).” (MPEP § 803.02, emphasis added).

The Examiner is also reminded that even where a provisional election of a single species is proper prior to examination on the merits, following election the Markush-type claim should be examined fully with respect to the elected species and further to the extent necessary to determine patentability. (MPEP § 803.02). The MPEP requires that should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim **will be extended** to non-elected species. (*Id.*, emphasis added).

As such, Applicants expressly reserve the right to traverse any subsequent divisions made by the Examiner of the present invention into “inventive groups” following the present provisional election of the species for examination.

Applicants have no intention of abandoning any non-elected subject matter and should it be necessary, Applicants expressly reserve the right to file one or more continuation and/or divisional applications directed to non-elected subject matter.

With regard to the required species elections, Applicants once again draw the Examiner's attention to M.P.E.P. § 803, which recites: “If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions.” No basis as to why a search of these categories would be burdensome, let alone seriously burdensome, has been set forth in the Official Communication, as required.

In addition to showing the serious burden, the Patent Office is also under an obligation to demonstrate that the species are independent and/or distinct. M.P.E.P. § 806.04(b). No basis has been provided in the Official Communication as to why the various members of the generic classes in question are independent and/or distinct. Without meeting

this obligation, the requirements have not been properly evinced. Furthermore, no evidence was provided why the instant elections are necessary in view of the claims and art.

The Applicants further submit that, under 37 C.F.R. § 1.141 and M.P.E.P. § 806.04(a), a reasonable number of species may still be claimed in one application. The Patent Office has not provided any explanation as to why the species could not be examined together. *See* M.P.E.P. § 808.01(a).

Accordingly, as no distinction was presented and no explanation of why the amount of species was seriously burdensome on the Examiner, the Applicants respectfully request reconsideration of the additional restriction and species elections, and requests their withdrawal.

**CONCLUSION**

Accordingly, for at least all of the above reasons, withdrawal of the requirement for restriction is requested and believed to be in order. Further and favorable consideration of all claims on record on the merits is respectfully requested.

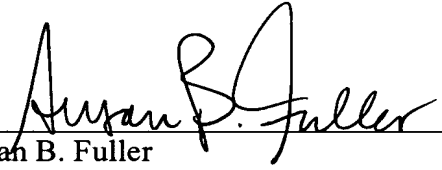
In the event of any questions, regarding this Response or the application in general, it would be very much appreciated if the Examiner would telephone the undersigned agent concerning such questions, so that the prosecution of the instant application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL L.L.P.

Date: September 22, 2005

By: \_\_\_\_\_

  
Susan B. Fuller

Registration No. 51,979

Suite 300  
12230 El Camino Real  
San Diego, California 92130  
(858) 509-7337